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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,109	01/26/2001	Allan S. Lau	4099-0003.31	8965

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EXAMINER

WINKLER, ULRIKE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.



**Office Action Summary**

Application No.

09/772,109

Applicant(s)

LAU ET AL.

Examiner

Ulrike Winkler

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8, 11, 25, 26, 29, 31-34, 37, 39 and 40 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

- 6) ☒ Claim(s) 1-8, 11, 25, 26, 29, 31-34, 37, 39 and 40 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.                      6) ☐ Other:



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### **DETAILED ACTION**

The Amendment filed August 4, 2003 (Paper No. 13) in response to the Office Action of January 28, 2003 is acknowledged and has been entered. Claims 9, 10, 12-24, 27, 28, 30, 35, 36 and 38 have been cancelled. Claims 1-8, 11, 25, 26, 29, 31-34, 37, 39 and 40 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Priority***

This application is a CIP of application 09/657881 and the provisional application 06/152854, claims that make reference to CrmA will only be granted the priority to the filing date of the instant application which is January 26, 2001.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on January 27, 2003 was filed before the mailing date of the first Office action on the merits mailed January 28, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 11, is attached to the instant Office action.



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***Claim Objections***

The objection to claims 12, 30 and 38 under 37 CFR 1.75(c) is **withdrawn** in view of Applicant's cancellation of the claims.

***Claim Rejections - 35 USC § 112***

The rejection of claims 1 and 3 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of Applicant's arguments.

The rejection of claim 1 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is **withdrawn** in view of Applicant's arguments.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claim 3 under 35 U.S.C. 102(b) as being anticipated by Dixit (U.S. Pat. No. 6,159,712) is **maintained** for reasons of record.



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Applicant's arguments filed August 4, 2003 (Paper No. 13) have been fully considered but they are not persuasive. In response to applicant's argument that the reference does not provide for the "use in producing one or more cytokines", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The mere recitation of newly-discovered function or property, inherently possessed by things in the prior art, does not cause the claim drawn to those things to distinguish over the prior art (See *In re Best, Bolton, and Shaw* 195 USPQ 430 (CCPA 1977), *In re Schreiber* 44 USPQ2d 1429)

The instant invention is drawn to a human cell line (a composition) that comprises the CrmA coding sequences. As the cell line need only be "capable of" expressing cytokines any human cell line that has been transformed with CrmA will read on the instant claim. In this instance the claim as written does not require the insertion of one or more a cytokine genes for expression into the cell line, all that is required is that the cell line be modified with the CrmA coding sequence. The burden is on applicant to show that the instant cell line would not be capable of producing cytokines.

Dixit V.M. disclose the transformation of MCF7 and BJAB cells (human derived cell line) with a vector encoding Crm-A (see examples 3, 4 and 5) The reference teaches that



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expression of CrmA provides resistance to the cell line against an apoptosis inducing stimulants (see claims). Therefore, the instant invention is anticipated by Dixit V.M.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1-8, 11, 25, 26, 29, 31-34, 37, 39 and 40 and rejected under 35 U.S.C. 103(a) as being unpatentable over Dixit (U.S. Pat. No. 6,159,712) and Lau et al. (U.S. Pat. No. 6,159,712). Applicant's arguments with respect to claim 1-8, 11, 12, 25, 26, 29-34 and 37-40 have been considered but are moot in view of the new ground(s) of rejection see below.

**New Rejection:**

Claims 1-8, 11, 12, 25, 26, 29-34 and 37-40 and rejected under 35 U.S.C. 103(a) as being unpatentable over Dixit (U.S. Pat. No. 6,159,712), Lau et al. (U.S. Pat. No. 6,159,712) and Suzuki et al. (Derwent Abstract XP-002170158; see IDS Paper No. 13; JP9-163983-A see PTO 892 translation of full patent included).

The instant invention is drawn to a composition, a cell line (claim 1). This cell line expresses a coding sequence for an anti-apoptotic protein, specifically CrmA (claims 2).



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For this office action, the preamble of the product-by-process claims were interpreted as “a composition of matter” (which are *products*.). Product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps. M.P.E.P. Section 2113 states that:

“[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

One vector carries the CrmA sequence and the other vector carries the PKR sequence. The cell line is treated with the priming agent, phorbol myristate acetate (PMA) and an inducing agent poly I:C.

Dixit V.M. teaches the transformation of MCF7 and BJAB cells (human derived cells line) with a vector encoding CrmA (see examples 3, 4 and 5). The reference teaches that expression of CrmA provides resistance to the cell line against an apoptosis inducing stimulants. The reference does not teach utilizing CrmA expression in a cell line for the production of cytokines.

Lau et al. teach a method of producing a cell that is able to over express cytokines wherein the cell comprises a vector containing PKR, and the cytokine expression is stimulated by induction using poly I:C and the priming agent PMA. Overexpression of PKR induced overproduction of the cytokines INF-alpha and INF-beta. The reference does not teach introducing two vectors into a cell one which encodes PKR and the other which encodes the anti apoptotic protein CrmA.



Suzuki et al. teaches the use of increasing the production of useful substances by transforming an apoptosis-suppressive gene, including CrmA, into a host animal cell that produces the useful substances (see abstract). The objective is to produce useful matter such as cytokines by inhibiting apoptosis of an animal cell which produces the cytokine (see paragraphs 0020 and 0023).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the antiapoptotic protein CrmA with the PKR cell line which is capable of overexpressing cytokines. Suzuki et al. suggest the use of combining an apoptosis-suppressive gene including CrmA for the production of cytokines. It is well established in the art that the apoptosis induction has many stimuli, including the induction by cytokines. In an effort to express cytokines from a cell the production and release of the cytokine into the medium/supernatant will have a negative effect on the cell producing the cytokine. This is a negative feedback loop normally would function to turn off cytokine production, however, cells that keep producing cytokine will eventually die because the effect is to trigger the apoptotic event. Once too much cytokine has been produced the cell is then stimulated to begin the path of self destruction. One having ordinary skill in the art would have been motivated to include CrmA in any cell line that is used for the expression of proteins, as taught by Lau and Suzuki et al., in order to inhibit apoptotic events. Therefore, the instant invention is obvious over of Dixit, Lau et al. and Suzuki et al.

### ***Conclusion***

No claims allowed.



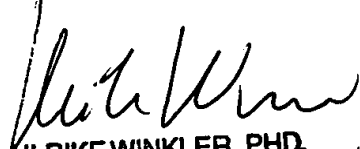
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-746-3162.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
ULRIKE WINKLER, PH.D.  
PATENT EXAMINER 10/20/03